

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration Florida District 555 Winderley Place Suite 200 Maitland Florida 32751

Telephone: 407-475-4700 FAX: 407-475-4768

VIA FEDERAL EXPRESS

Reference:

Customs Entry No.DM4-0086124-9.

Product:

Fresh Produce

WARNING LETTER

FLA-02-57

September 6, 2002

Alan Michael Parr, President Team Produce International, Inc. 8850 NW 20th Street Miami, Florida 33172

Dear Mr. Parr:

On June 12, 2002, your firm offered for import into the United States 200 cartons of French Beans, 20 cartons of Green Zucchini and 20 cartons of Sunburst Squash under U. S. Customs Service entry DM4-0086124-9. On June 12, 2002, the U. S. Food and Drug Administration (FDA) detained the products without physical examination because the product appeared to be adulterated due to the presence of pesticides. On June 28, 2002, the products were refused entry into the United States.

Section 801(a) of the Federal Food, Drug, and Cosmetic Act ("Act") directs the Secretary of the Treasury to issue a Notice of Refusal when it appears from examination of samples, or otherwise, that an imported shipment is in violation. This Section also orders the destruction of any such shipment refused admission, unless it is exported within 90 days of the date of the notice, or within such additional time as may be permitted pursuant to such regulations. Under the Act, the product under entry DM4-0086124-9 is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain pesticide chemicals, which is in violation of Section 402(a)(2)(B).

On June 28, 2002, FDA documented the substitution of the refused product (under entry #DM4-0086124-9). On July 10, 2002, you provided FDA with a signed affidavit and supporting invoices demonstrating the sale, into interstate commerce, of the refused shipment.

This is a violation of Title 21, Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA. Since the articles were not held and there was an attempt to evade regulation, the FDA has requested U.S. Customs to increase your bond, and require future entries from your firm to be held in a bonded warehouse until FDA makes a final decision as to admissibility.

It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act, and the regulations promulgated thereunder. We wish to remind you that making fraudulent misrepresentations or false statements to federal officials are criminal offences under Title 18, United States Code (18 USC), 542 and 1001. When evidence demonstrates the article presented to FDA for examination is not from the original entry, but was substituted for the entry, the article may be seized under Title 19 section 1595a (c). Liquidated damages may also be assessed for articles not redelivered. Criminal charges of entry contrary to law (18 USC 545) may result in addition to the charges mentioned above. Criminal offenses can result in imprisonment or fines or both.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or detention without examination of future shipments. Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished. Your written reply should be addressed to the Food and Drug Administration, Attention: Christine M. Humphrey, Compliance Officer, 6601 NW 25th Street, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Emma R. Singleton Director, Florida District

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